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of Correction

FROM: Paul D. Bianco, Ph.D.

REFERENCE: 782-A02-013-3

DIRECT TEL: 305-931-9620  
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## MESSAGE:

PLEASE DELIVER THE FOLLOWING COMMUNICATION CONCERNING THE BELOW  
IDENTIFIED CASE

Patentee: P. Bonutti

Confirmation No.: 7485

Application No.: 09/925,551

Group Art Unit: 3731

Patent No.: 6,899,722

Examiner: Bui, Vy

Filed: August 9, 2001

Attorney Docket No: 782-A02-013-3

Issued: May 31, 2005

For: SUTURE ANCHOR

1. Request for Certificate of Correction of Patent (2 pgs)
2. Certificate of Correction (duplicate)
3. Copy of Response to Office Action (13 pgs)

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JUL 22 2005

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patentee: P. Bonutti

Application No.: 09/925,551

Patent No.: 6,899,722

Filed: August 9, 2001

Issued: May 31, 2005

For: SUTURE ANCHOR

Confirmation No.: 7485

Group Art Unit: 3731

Examiner: Bui, Vy

Attorney Docket No: 782-A02-013-3

**REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT  
UNDER 37 C.F.R. § 1.322**

ATTN:

Certificate of Corrections Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

Sir:

It is noted that an error appears in the above-identified patent. The exact locations and nature of these errors are as follows:

Column 12, Claim 11, Line 20

the phrase "in a press, operating the press..."

should read "in a press, and operating the press..."

Column 12, Claim 11, Line 24

the phrase "body tissue includes freeze body tissue.."

should read "body tissue includes freeze drying body tissue.."

Column 12, Claim 18, Line 61, change "lume" to --lumen--

Column 14, Claim 29, Line 10, change "include" to --includes--

A copy of the Amendment for this case filed October 12, 2004 is enclosed. As claims 86, 91 and 102, which issued as claims 11, 18 and 29 were allowed in the form presented in this Amendment, issued claims 11, 18 and 29 should read as found in the Amendment and should be corrected as noted above. Additionally, it is respectfully submitted that these errors are of a clerical error and attributable solely to Office mistake. Accordingly, a Certificate of Correction is requested. Attached hereto in duplicate is Form PTO-1050 with at least one copy being suitable for printing. Please send the Certificate of Correction to the undersigned at the address noted. If there are any questions regarding this Request, a telephone call to the undersigned would be appreciated since this should expedite issuance of the Certificate.

As these errors are solely attributable to an Office mistake, no fee is believed to be due. However, should any fee be due, please charge the appropriate fee to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A02-013-3)

Respectfully submitted,



Paul D. Bianco, Reg. #43,500

Enclosures

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CERTIFICATE OF CORRECTION****RECEIVED  
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PATENT NO. : 6,899,722

DATED : May 31, 2005

INVENTOR(S) : Peter M. Bonutti

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12, Line 20  
the phrase "in a press, operating the press..."  
should read "in a press, and operating the press..."

Column 12, Line 24  
the phrase "body tissue includes freeze body tissue.."  
should read "body tissue includes freeze drying body tissue.."

Column 12, Line 61, change "lume" to --lumen--

Column 14, Line 10, change "include" to --includes--

MAILING ADDRESS OF SENDER: Paul D. Bianco  
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PATENT NO. 6,899,722

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This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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MESSAGE:

PLEASE DELIVER THE FOLLOWING COMMUNICATION CONCERNING THE BELOW IDENTIFIED CASE

Applicant(s): P. Boudatti	Confirmation No. 7485
Application No.: 09/925,551	Group Art Unit: 3791
Filed: August 9, 2001	Examiner: V. Bui
Re: SUTURE ANCHOR	Attorney Docket No: 782-A02-013-3

1. Response to Office Action (12 pages)

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 ATTY/REG: V. G. Bui  
 On: October 12, 2004

Paul Boudatti  
 Name of Person Transmitting Facsimile

*K. Chisholm*  
 Signature of Person Transmitting Facsimile

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PAGE 003 \* 6/18 AT 10/12/2004 1:55:36 PM [Eastern Daylight Time] \* SVR:USPTO-EFXXRF-6/26 \* DNIS:2738300 \* CSID:305 416 4489 \* DURATION (mm:ss):04:26

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): P. Bonutti

Application No.: 09/925,551

Filed: August 9, 2001

For: SUTURE ANCHOR

Confirmation No. 7485

Group Art Unit: 3731

Examiner: V. Bui

Attorney Docket No: 782-A02-013-3

**AMENDMENT AFTER FINAL UNDER 37 C.F.R. § 1.116**

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**COPY**

Dear Sir:

In response to the Office Action mailed August 12, 2004, Applicant hereby submits the following amendments, remarks, and request for reconsideration.


Applicant respectfully requests entry of this amendment under the provisions of 37 C.F.R. §1.116(a) in that the amendment and remarks below place the application and claims in condition for allowance, or, at least, present the application in better form for appeal. Reconsideration and allowance of the pending claims in view of the following are respectfully requested.

**CERTIFICATE OF FACSIMILE TRANSMISSION**

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ATTENTION: Patent Examiner Vy Q. Bui

On October 12, 2004

Dinah Fuentes  
Name of Person Transmitting Facsimile

  
Signature of Person Transmitting Facsimile

Applicant(s): P. Bonutti  
Application No.: 09/925,551  
Examiner: V. Bui

**Amendments to the Claims**

1.-71. (Cancelled)

72. (Currently amended) A method as set forth in claim ~~71~~ 76 wherein said step of freeze drying the body tissue includes removing liquid from the body tissue.

73. (Currently amended) A method as set forth in claim ~~71~~ 76 further including the step of forming a sheet of body tissue and removing a portion from the sheet of body tissue.

74.-75. (Cancelled)

**COPY**

76. (Previously presented) A method of anchoring a suture, said method comprising:  
rotating a cutting tool and moving the rotating cutting tool into body tissue;  
rotating a thin elongated member and moving the rotating thin elongated member into the body tissue;  
freeze drying body tissue;  
inserting a suture into a passage in the freeze dried body tissue; and  
inserting the freeze dried body tissue into a patient's body with the suture extending the passage in the freeze dried body tissue, wherein said steps of rotating a cutting tool and moving the rotating cutting tool into the body tissue and said steps of rotating a thin elongated member and moving the rotating thin elongated member into body tissue are performed together.

77. (Currently amended) A method as set forth in claim ~~71~~ 76 further including the step of removing cartilage from a body, said step of freeze drying body tissue includes freeze drying the cartilage.

78. (Currently amended) A method as set forth in claim ~~71~~ 76 further including the

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step of removing at least a portion of a tendon from a body, said step of freeze drying body tissue includes freeze drying the tendon.

79. (Currently amended) A method as set forth in claim ~~71~~ 76 further including the step of removing at least a portion of a bone from a body, said step of freeze drying body tissue includes freeze drying the bone.

80. (Currently amended) A method as set forth in claim ~~71~~ 76 wherein said step of inserting the freeze dried body tissue into a patient's body includes moving the freeze dried body tissue into the patient's body with a first end portion of the freeze dried body tissue leading and a second end portion of the freeze dried body tissue trailing and applying force against the second end portion of the freeze dried body tissue.

**COPY**

81. (Currently amended) A method as set forth in claim ~~71~~ 76 wherein said step of freeze drying body tissue includes forming a sheet of freeze dried body tissue, said method further includes moving a member into the sheet of freeze dried body tissue.

82. (Currently amended) A method as set forth in claim ~~71~~ 76 further including the step of cutting body tissue of an animal other than a human, said step of inserting the freeze dried body tissue into a patient's body includes inserting the freeze dried body tissue into a human patient's body.

83. (Previously presented) A method as set forth in claim ~~71~~ 76 wherein said step of inserting the freeze dried body tissue into a patient's body includes positioning the freeze dried body tissue in the patient's body at a location where the freeze dried body tissue is exposed to body fluid to enable the freeze dried body tissue to absorb body fluid.

84. (Previously presented) A method as set forth in claim ~~71~~ 76 further including the



Applicant(s): P. Bomuti  
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step of removing bone from the patient's body, said step freeze drying body tissue includes freeze drying the bone removed from the patient's body.

85. (Previously presented) A method as set forth in claim ~~71~~ 76 further including the step of removing bone from a body other than the patient's body, said step of freeze drying body tissue includes freeze drying the bone removed from a body other than the patient's body.

86. (Previously presented) A method as set forth in claim ~~71~~ 76 further including the steps of placing the body tissue in a press, and operating the press to apply pressure against the body tissue in the press to shape the body tissue in the press during operation of the press, said step of freeze drying body tissue includes freeze drying body tissue removed from the press.

87. (Previously presented) A method as set forth in claim ~~71~~ 76 further including the step of piercing freeze dried body tissue to at least partially form the passage.

88. (Previously presented) A method as set forth in claim ~~71~~ 76 further including the step of moving a cutting tool to cut freeze dried body tissue and at least partially form a surface of the freeze dried body tissue.

**COPY**

89. (Previously presented) A method as set forth in claim ~~71~~ 76 wherein said step of inserting the freeze dried body tissue into the patient's body includes moving the freeze dried body tissue into the patient's body with the freeze dried body tissue in a first orientation, and applying force against the freeze dried body tissue to pivot the freeze dried body tissue from the first orientation to a second orientation while the freeze dried body tissue is in the patient's body.

90. (Previously presented) A method as set forth in claim 89 wherein said step of applying force against the freeze dried body tissue includes tensioning the suture.

Applicant(s): P. Bonutti  
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91. (Currently amended) A method of retaining portions of first and second tissue elements in a patient's body against movement relative to each other, said method comprising the steps of freeze drying body tissue, engaging at least one of the first and second tissue elements in the patient's body with the freeze dried body tissue, and securing the first and second body tissue elements together by transmitting force between the first and second tissue elements through the freeze dried body tissue, such that the first and second tissue elements are retained against movement relative to each other, wherein the first tissue is bone tissue and the second tissue is soft tissue.

92. (Previously presented) A method as set forth in claim 91 wherein said step of freeze drying the body tissue includes removing liquid from the body tissue.

93. (Previously presented) A method as set forth in claim 91 further including the step of forming a sheet of body tissue and removing a portion from the sheet of body tissue.

94. (Previously presented) A method as set forth in claim 91 further including the step of rotating a cutting tool and moving the rotating cutting tool into body tissue.

95. (Previously presented) A method as set forth in claim 94 further including the step of rotating a thin elongated member and moving the rotating thin elongated member into the body tissue.

**COPY**

96. (Previously presented) A method of retaining portions of first and second tissue elements in a patient's body against movement relative to each other, said method comprising:  
rotating a cutting tool and moving the rotating cutting tool into body tissue;  
rotating a thin elongated member and moving the rotating thin elongated member into the body tissue;  
freeze drying body tissue;

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engaging at least one of the first and second tissue elements in the patient's body with the freeze dried body tissue; and

transmitting force between the first and second tissue elements through the freeze dried body tissue, wherein said steps of rotating a cutting tool and moving the rotating cutting tool into the body tissue and said steps of rotating a thin elongated member and moving the rotating thin elongated member into body tissue are performed together.

97. (Previously presented) A method as set forth in claim 91 further including the step of removing cartilage from a body, said step of freeze drying body tissue includes freeze drying the cartilage.

98. (Previously presented) A method as set forth in claim 91 further including the step of removing at least a portion of a tendon from a body, said step of freeze drying body tissue includes freeze drying the tendon.

**COPY**

99. (Previously presented) A method as set forth in claim 91 further including the step of removing at least a portion of a bone from a body, said step of freeze drying body tissue includes freeze drying the bone.

100. (Previously presented) A method as set forth in claim 91 further including the step of moving the freeze dried body tissue into the patient's body with a first end portion of the freeze dried body tissue leading and a second end portion of the freeze dried body tissue trailing and applying force against the second end portion of the freeze dried body tissue.

101. (Previously presented) A method as set forth in claim 91 wherein said step of freeze drying body tissue includes forming a sheet of freeze dried body tissue, said method further includes moving a member into the sheet of freeze dried body tissue.

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102. (Previously presented) A method as set forth in claim 91 further including the step of cutting body tissue of an animal other than a human, said step of engaging at least one of the first and second tissue elements in a patient's body includes inserting the freeze dried body tissue into a human patient's body.

103. (Previously presented) A method as set forth in claim 91 wherein said step of engaging at least one of the first and second tissue elements in a patient's body includes positioning the freeze dried body tissue in the patient's body at a location where the freeze dried body tissue is exposed to body fluid to enable the freeze dried body tissue to absorb body fluid.

104. (Previously presented) A method as set forth in claim 91 further including the step of removing bone from the patient's body, said step freeze drying body tissue includes freeze drying the bone removed from the patient's body.

**COPY**

105. (Previously presented) A method as set forth in claim 91 further including the step of removing bone from a body other than the patient's body, said step of freeze drying body tissue includes freeze drying the bone removed from a body other than the patient's body.

106. (Previously presented) A method as set forth in claim 91 further including the steps of placing the body tissue in a press, and operating the press to apply pressure against the body tissue in the press to shape the body tissue in the press during operation of the press, said step of freeze drying body tissue includes freeze drying body tissue removed from the press.

107. (Previously presented) A method as set forth in claim 91 further including the step of piercing freeze dried body tissue to at least partially form a passage in the freeze dried body tissue.

108. (Previously presented) A method as set forth in claim 91 further including the step

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of moving a cutting tool to cut freeze dried body tissue and at least partially form a surface of the freeze dried body tissue.

**COPY**

Applicant(s): P. Bonatti  
Application No.: 09/925,551  
Examiner: V. Bui

### Remarks

Claims 72, 73, and 76-108 are pending in the application and are presented for the Examiner's review and consideration. Claims 72, 73, 77-89, and 91 have been amended and claims 71, 74, and 75 have been cancelled. Applicant believes the claim amendments, cancellations, and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

### Interview Summary

The Applicant, through Applicant's attorney, held a telephonic interview with Examiner Vy Q. Bui on October 7, 2004. Applicant appreciates the courtesies extended to Seth Blum during this interview. The Examiner stated that in view of Applicant's arguments, the final rejection of claim 91 would require additional review. The Examiner also indicated that claim 91 as presented herein distinguishes over the prior art and would be considered favorably.

Accordingly, Applicant respectfully submits that the amendments and remarks presented herein reflect those discussed during the interview.

**COPY**

### Allowed Claims

Applicant acknowledges with appreciation the indication that claims 76 and 96 are in condition of allowance.

### 35 U.S.C. §102(e) and §103(a)-McGuire.

Claims 71-75, 79-80, 82-85, 87-92, 94-95, 99-100, 102-105, and 107-108 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 5,865,834 to McGuire ("McGuire"). Claims 77-78, 81, 86, 93, 97-98, 101, and 106 were rejected under 35 U.S.C. §103(a) as unpatentable over McGuire.

Claims 71, 74, and 75 have been cancelled, rendering the rejection of these claims moot.

Claims 72, 73, and 77-90 have been amended to depend from allowed claim 76.

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Accordingly, Applicant respectfully submits that dependent claims 72, 73, and 77-90 are also allowable over McGuire.

For the reasons set forth below, Applicant respectfully submits that claims 91-95, and 97-108 are patentable over McGuire. The Examiner states that:

**COPY**

McGuire (Figs. 1, 4a-4b, 5-6; col 9, ll. 60-64) discloses autogenous bone or freeze-dried bone anchor/plug 25, suture 27, cutting tool 33 to cut out autogenous bone plug 25, elongate member/drill to form passages for suture 27 in bone plug 25. Allograft bone plug can be provided from a freeze-drying process.

Noticing that holes/passages 27 are formed by drilling through anchor/bone plug 25 (Col. 6, lines 34-36) and have a larger diameter than that of the suture (Fig. 4a-4b). Therefore, the suture of McGuire can slide freely through the passages drilled in the bone anchor/plug 25 as recited in the independent claim 71. In addition, notice that bone anchor/plug 25 secures first tissue (femur 14) and second tissue (tibia 12) and retains first tissue (femur 14) and second tissue (tibia 12) against relative movement relative to each other as recited in the independent claim 91 because anchor/plug 25 does not allow a separation/relative movement of the first tissue (femur 14) linearly away from second tissue (tibia 12).

McGuire relates to the field of arthroscopic surgery, particularly anterior cruciate ligament reconstruction. (Col. 1, lns. 18-20). The two major bones that meet at the knee joint are the tibia 12 and the femur 14, a bone tunnel 16 is drilled through each of these two bones. (Col. 2, lns. 17-19). The semitendinosus tendon 20 and/or gracilis 21 is extended between both of the bone plugs. (Col 6, lns. 57-58). Sutures are also used through the suture holes to attach the tendon to each of the bone plugs. (Col. 6, lns. 62-63).

The sutures may be pulled on to properly tension and locate the graft within the bone tunnels. (Col. 9, lns 25-26). The sutures may be pulled on to properly tension and locate the graft with the bone tunnels. (Col. 9, lines 25-26). Fixation of the graft can be accomplished with a headless cannulated interface screw. (Col. 9, lns. 30-31).

Claim 91 recites a method of retaining portions of first and second tissue elements in a patient's body against movement relative to each other. The method includes the step of freeze drying body tissue. The freeze dried body tissue engages at least one of the first and second tissue elements in the patient's body, securing the first and second body tissue elements together.

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The first and second body tissue elements are secured together by transmitting force between the first and second tissue elements through the freeze dried body tissue, such that the first and second tissue elements are retained against movement relative to each other.

As noted above, McGuire discloses a composite graft for a reconstruction ligament in a knee. A knee is a hinged joint connecting the femur and the tibia. When the knee is moved in flexion or extension the tibia moves relative to the femur, rotating about a central axis of rotation. There is also a slight translational and twisting component in this motion. The knee is held together by four ligaments. A ligament is a structure in the knee that holds the bones together and helps to control joint movement or motion.

**COPY**

The role of the anterior cruciate ligament (ACL) is to hold the tibia tightly to the femur as the knee moves in flexion or extension. The ACL substantially prevents the lower tibia bone from migrating anteriorly from underneath the femur. The ACL also substantially prevents the lower tibia bone from rotating (twisting). The result is that an individual, such as an athlete, can rapidly turn, twist, and resume running at full speed without the knee collapsing.

The purpose of ACL reconstruction surgery is to repair a torn or damaged ACL, to tighten the knee, restoring stability to the knee. After ACL reconstruction surgery, the knee gradually returns to full flexibility and stability, allowing for full range of motion.

The composite graft of McGuire includes a pair of bone plugs with a tendon wrapped there around. The tendon can be secured to the bone plug with sutures. The bone plugs are inserted into the bone tunnels in the femur and tibia and affixed thereto, replacing the ACL. The purpose of replacing the ACL is to provide stability to the knee joint, allowing for a full range of motion in the knee. The replacement ACL allows relative movement between the femur and the tibia, allowing the tibia to rotate relative to the femur. The preventing of relative motion of the tibia relative to the femur is specifically taught against by McGuire and would defeat the underlying intended purpose of McGuire, which is to restore stability and full range of motion to the knee. As such, McGuire does not disclose using the bone plugs to secure the femur to the tibia, preventing relative movement with respect to each other.

Additionally, claim 91 now recites that the first tissue is bone tissue and the second tissue



Applicant(s): P. Bomtti  
Application No.: 09/925,551  
Examiner: V. Bui

is soft tissue. McGuire discloses a graft coupling a first bone (femur) to a second bone (tibia).

Accordingly, Applicant submits that McGuire does not teach or suggest all of the elements of claim 91. In light of the foregoing, independent claim 91 is respectfully submitted to be patentable over McGuire. As claims 92-95 and 97-108 depend from claim 91, these dependent claims necessarily include all the elements of their respective base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over McGuire at least for the same reasons.

**COPY**

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due for this submission. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 782-A03-013-3).

Respectfully submitted,



Paul D. Bianco, Reg. # 43,500

Customer Number: 33771  
Paul D. Bianco  
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